FEB 0 7 2013

510(k) SUMMARY
NLT SPINE's eSPIN

Sponsor:

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Contact Person:

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Date Prepared: February 6, 2013

Name of Device: eSPIN

Common or Usual Name: Arthroscope and Accessories

Classification Name: Arthroscope and Accessories
21 CFR §880.1100
Product Code: HRX

Predicate Devices:

NLT SPINE's eSPIN (K120553)

Purpose of the Special 510(k) notice:

The eSPIN is a modification to previously cleared K120553 eSPIN and can be compared to the cleared device as follows:

Feature	Predicate NLT SPINE eSPIN Discectomy System (K120553)	Modified NLT SPINE eSPIN Discectomy System
Intended Use and Indication	The eSPIN is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with	Same

Feature	Predicate NLT SPINE eSPIN Discectomy System (K120553)	Modified NLT SPINE eSPIN Discectomy System
	degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems	
Product Code	HRX Arthroscope, 21 CFR 888.1100, Class II	Same
Principal Operator	Physician	Same
Use Location	Operating room or Medical Suite	Same
Operating Principal	Percutaneous or open surgical Discectomy system with standard surgical accessories	Same
Functions of Included Devices	Dilatation Access Excision	Dilatation Access Excision Irrigation Suction
Mechanics of Action	Percutaneous or open surgical Discectomy system with standard surgical accessories	Same
Target Anatomy	Intervertebral procedure for L2-S1 spinal segments	Same
Biocompatibility for Intended Use	Yes	Yes
Single Use	Yes (Tips)	Yes (Tips)
Configuration	Straight during insertion, and curved during rotation by its articulation	Straight during insertion, and curved during rotation by its articulation

Intended Use

The eSPIN is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems.

Technological Characteristics

The eSPIN powered system consists of a hand-held instrument (manipulator unit), a set of disposable tips, and direct connection to a motor via motor adaptor. In addition, set of instruments are to access the disc space and to position the manipulator unit for discectomy. The eSPIN needs to be connected to an electrical motor or drill. The required motor/drill specifications are provided in the eSPIN User Manual.

The primary changes from the cleared eSPIN are:

- Addition of Suction tube and irrigation system
- Minor modifications to the device design

Performance Data

The following testing demonstrated that the eSPIN is substantially equivalent to its predicate:

- Bending mechanism durability of manipulator unit
- Verification of tip bending angle
- Verification of discectomy cleaning work limits
- Verification of motor parameters
- Tip attachment strength under tensile force
- Durability of tip bristle and tip under rotational and tensile loading
- Biocompatibility evaluation in accordance with ISO 10993
- Cadaver studies to evaluate whether the device breaches annulus and confirm radiopacity of tip under X-ray

Substantial Equivalence

The eSPIN has the same intended use and indications, principles of operation, and technological characteristics as the predicate. The minor differences in the eSPIN technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the eSPIN is as safe and effective as the predicate. Thus, the eSPIN is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NLT Spine, Limited
% Hogan and Lovells US, LLP
Dr. John Smith
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

February 7, 2013

Re: K130057
Trade/Device Name: eSPIN
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: January 09, 2013
Received: January 09, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130057

Device Name: eSPIN

Indications for Use:

The eSPIN is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems).

Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.02.15 11:53:32 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K130057